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Supreme Court, U.S.
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No. 96-125

In The

Supreme Court of the United States

October Term, 1995

LYNNBROOK FARMS,
an Illinois General Partnership,

Petitioner,

vs.

SMITHKLINE BEECHAM CORPORATION,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Seventh Circuit

RESPONDENT SMITHKLINE BEECHAM CORPORATION'S BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Are Petitioner's state law claims for harm to animals purportedly caused by animal vaccines, as set forth in its Amended Complaint, preempted by federal law where the United States Department of Agriculture ("USDA"), acting within the scope of its delegated authority under the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151-159, clearly expressed its intent to preempt all state law – including common law damages actions – which would impose requirements different from or in addition to those imposed by USDA regarding the safety, efficacy, purity, potency or labeling of animal vaccines and where it is undisputed that the vaccines at issue complied with USDA requirements?

PARTIES TO THE PROCEEDINGS

Pursuant to Rule 29.6, respondent SmithKline Beecham Corporation states that it has the following non-wholly owned subsidiaries in the United States: SmithKline Beecham Holdings Corp. and SmithKline Beecham Consumer Healthcare L.P. Respondent's parent company is SmithKline Beecham plc, a public limited company incorporated under the laws of England.

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RESPONDENT'S BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

Respondent SmithKline Beecham Corporation ("SBC") respectfully requests that this Court deny the petition of Lynnbrook Farms ("Lynnbrook") for a Writ of Certiorari which seeks review of the opinion issued below in this case by the United States Court of Appeals for the Seventh Circuit.

OPINIONS AND ORDERS BELOW

The opinion of the United States Court of Appeals for the Seventh Circuit is reported at 79 F.3d 620 (7th Cir. 1996), and included in Pet. App. at A-1. The opinion of the United States District Court for the Central District of Illinois, Peoria Division, is reported at 887 F. Supp. 1100 (C.D. Ill. 1995), and included in Pet. App. at A-23.

JURISDICTIONAL STATEMENT

The United States Court of Appeals for the Seventh Circuit entered judgment on March 21, 1996. (Pet. App. A-1) Lynnbrook filed a petition for rehearing and suggestion for rehearing *en banc* on April 3, 1996, which the court denied on April 22, 1996. (Pet. App. A-38)

Lynnbrook filed a petition for a Writ of Certiorari with this Court on July 22, 1996. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISION, STATUTES AND REGULATIONS INVOLVED

The supremacy clause of the United States Constitution, Article VI, cl. 2 is included in Resp. App. at A-32.

The Virus-Serum-Toxin Act ("VSTA"), 21 U.S.C. §§ 151-159 (1913) (amended 1985) is included in Resp. App. at A-33. The legislative history to the 1985 amendments to VSTA, S. Rep. No. 99-145, 99th Cong. 1st Sess. at 338-39 (1985) *reprinted in* 1985 U.S. Code Congressional &

Administrative News 1676, 2004-5, is included in Pet. App. at A-45.

The regulations promulgated pursuant to VSTA by the United States Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS"), 9 C.F.R. Parts 101-124, have been lodged with the Clerk of Court. APHIS' declaration of preemption, 57 Fed. Reg 38758, 38759 (Aug. 27, 1992), is included in Pet. App. at A-50. Correspondence regarding the scope of APHIS' declaration of preemption from Acting Administrator of APHIS, Terry L. Medley, to Senator Paul D. Wellstone, dated December 22, 1995, is included in Resp. App. at A-29.

STATEMENT OF THE CASE

The Declaration of Preemption

This case involves the validity and application of an *express* declaration of preemption of state law made by a federal agency. Pursuant to the Virus-Serum-Toxin Act ("VSTA"), 21 U.S.C. §§ 151-159 (1913) (amended 1985), the United States Department of Agriculture ("USDA") is authorized to promulgate "such rules and regulations as may be necessary" to prevent the manufacture, sale and distribution of any "worthless, contaminated, dangerous or harmful" animal vaccines. (Resp. App. 34-35) Within USDA, the Animal and Plant Health Inspection Service ("APHIS") is responsible for administering VSTA.

Following two court decisions holding that VSTA did not apply to the production and sale of animal vaccines made and sold within a single state, Congress in 1985 amended VSTA to place both "intrastate" and "interstate" animal vaccines under federal control. (S. Rep. No. 99-145, 99th Cong. 1st Sess. at 338-39 (1985), *reprinted in* 1985 U.S. Code Congressional & Administrative News 1676, 2004-5; Pet. App. A-45; 21 U.S.C. § 151; Resp. App. 33) In doing so, Congress declared that federal regulation of all animal vaccines was necessary to prevent and eliminate burdens upon interstate and foreign commerce. (21

U.S.C. § 159; Resp. App. 38-39) In the legislative history, Congress also expressed its unequivocal desire for "uniform national standards" for animal vaccines manufactured and sold in the United States. (S. Rep. No. 99-145, 99th Cong. 1st Sess. at 338-39; Pet. App. A-46)

Citing its intent to accomplish these precise congressional goals, APHIS made the following declaration of preemption of state law on August 27, 1992, in response to comments made during a rulemaking:

> Seven commenters indicated that States should have the authority to add to Federal restrictions, as appropriate, based on a need to protect animal or human health and safety so long as such restrictions do not lessen the effect of Federal regulations. APHIS agrees with the comment that States should not be allowed to lessen the effect of Federal restrictions on the distribution and use of veterinary biological products. *APHIS, however, does not agree that States should be allowed to add various restrictions as appropriate, based upon a need to protect domestic animals or the public health, interest, or safety. Any restrictions, other than those which are necessary to address a local disease condition should be Federally imposed so that they are uniform nationwide.*
>
> The legislative history relating to the 1985 amendments to the Act, which extends USDA's authority over veterinary biologics, clearly expresses Congressional intent that Federal regulation of veterinary biologics is needed to prevent and eliminate burdens on commerce and that there is a need for uniform national standards regarding these products. Therefore, *States are not free to impose requirements which are different from or in addition to those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the*

> *regulations under the Act may not be imposed by the States.* Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent and efficacious.
>
> * * *
>
> *[W]here safety, efficacy, purity and potency of biological products are concerned, it is the agency's intent to occupy the field. This includes but is not limited to the regulation of labeling.* Under the Act, Congress clearly intended that there be national uniformity in the regulation of these products.

(57 Fed. Reg. 38758, 38759 (Aug. 27, 1992); Pet. App. A-53 – A-56) (Emphasis added.)

In response to a congressional inquiry in December 1995, APHIS confirmed its intent to preempt *all* state law – including common law damages actions – which would impose requirements upon animal vaccine manufacturers different from or in addition to those imposed by APHIS regarding the safety, efficacy, purity, potency and labeling of animal vaccines. (Resp. App. 29-30) The confirmation of the scope of APHIS' declaration of preemption came after three courts, including the district court in this case, held that federal law preempted the plaintiffs' state law claims in actions alleging harm to cattle by vaccines where it was undisputed that the vaccines at issue fully complied with APHIS' requirements. (*Lynnbrook Farms v. SmithKline Beecham Corp.*, 887 F. Supp. (C.D. Ill. 1995); Pet. App. A-23; *Brandt v. The Marshall Animal Clinic*, 540 N.W.2d 870 (Minn. Ct. App. 1995); *Murphy v. SmithKline Beecham Animal Health*, 898 F. Supp. 811 (D. Kan. 1995)).

Following the Minnesota Court of Appeals decision in *Brandt*, the plaintiffs in that case enlisted the aid of Senator Paul D. Wellstone of Minnesota in an effort to cause APHIS to change course. By letter dated December 6, 1995, Senator Wellstone officially requested APHIS to "clarify" its preemption declaration – *i.e.*, to specify that

state tort actions were *not* preempted – before December 26, 1995, so that the Brandts could wield APHIS' "clarification" to their benefit when seeking discretionary review of the Minnesota Court of Appeal's decision before the Minnesota Supreme Court. In correspondence dated December 22, 1995, the Acting Administrator of APHIS, Terry L. Medley, responded to Senator Wellstone's inquiry. (Resp. App. 29-30) Referring to APHIS' final rule of August 27, 1992, which contained APHIS' declaration of preemption, Mr. Medley stated in part:

> *We stated in that rule that in order to maintain uniform national standards regarding veterinary biological products (including labeling) States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product.* We promulgated this rule in response to regulatory actions by certain States which intended to impose requirements concerning USDA licensed veterinary biological products which were different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product.
>
> *Our intent in promulgating the rule was, and continues to be, to preempt states from imposing requirements either through statutes, regulations, or other means, that are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product. Such requirements would include, but are not limited to, production, testing, distribution or labeling requirements.* We did not intend to preempt common law action damages arising from noncompliance with USDA regulatory standards.

(Resp. App. 29-30) (Emphasis added.)

Proceedings Before The District Court

Petitioner Lynnbrook filed this action on May 18, 1994, in the United States District Court for the Central District of Illinois, Peoria Division. The district court exercised jurisdiction under 28 U.S.C. § 1332.

In its Amended Complaint, Lynnbrook contended that its cattle were injured after being vaccinated in mid-1992 with two animal vaccines manufactured and sold by SBC – *CattleMaster 4 and Ultrabac 7/Somubac. (Resp. App. 1-16) According to Lynnbrook, the vaccines were either inefficacious in that they failed to protect against diseases that they were designed to counteract or alternatively, unsafe in that the vaccines caused other harm to the cattle. (*Id.*) Lynnbrook sought recovery against SBC upon separate theories of strict liability, negligence, misrepresentation, false advertising, and breach of implied warranties of merchantability and fitness. (*Id.*)

On November 2, 1994, SBC moved for summary judgment in its favor on all counts of the Amended Complaint on the grounds that federal law preempted all of the state law claims asserted by Lynnbrook. In support of its motion for summary judgment, SBC submitted the Affidavit of Cyril G. Gay, D.V.M., Ph.D. (Resp. App. 17-24) Dr. Gay testified that each of the vaccines at issue was specifically licensed by the USDA through APHIS. (Resp. App. A-20 – A-21) Through the licensure process and through post-licensure testing and evaluation, APHIS necessarily determined that each of the vaccines involved in the litigation satisfied all of APHIS' requirements for purity, safety, potency and efficacy. (Resp. App. 21) In addition, APHIS specifically approved in writing the text, layout and design of all labeling, packaging and product inserts for the vaccines. (Resp. App. 21)

Lynnbrook submitted *no evidence* in its resistance to the motion for summary judgment to controvert the testimony of Dr. Gay that the vaccines at issue fully satisfied all of APHIS' standards for safety, efficacy, purity, potency and labeling. Instead, Lynnbrook argued that

compliance with APHIS standards was neither dispositive nor a defense to liability because APHIS' requirements were intended to be only "minimum standards." Moreover, Lynnbrook stipulated that *no* discovery was required to adjudicate the preemption issue and invited SBC to seek a court order staying discovery during the pendency of the motion. (Resp. App. 25-26) SBC agreed and the district court entered such an order on February 15, 1995. (Resp. App. 27-28)

On March 30, 1995, Chief Judge Michael M. Mihm of the United States District Court for the Central District of Illinois, Peoria Division, entered findings of fact and conclusions of law, granted SBC's motion for summary judgment and entered final judgment in SBC's favor, dismissing with prejudice Lynnbrook's Amended Complaint in its entirety. (Pet. App. A-23)

Applying controlling precedents of this Court, the district court analyzed the validity and scope of APHIS' declaration of preemption. (Pet. App. at A-26 – A-29) Specifically, the district court considered: (1) whether the agency intended to preempt state law, including common law damages actions; (2) whether the agency acted within the scope of its delegated authority and acted neither arbitrarily, capriciously nor manifestly contrary to the statute the agency is authorized to administer; and (3) whether the plaintiff's state law claims fall within the scope of the declaration of preemption. (Pet. App. at A-29 – A-37)

As to the first question, the district court concluded that APHIS intended to preempt all state law, including state tort actions, which would impose requirements different from or in addition to those imposed by APHIS regarding the safety, efficacy, potency, purity and labeling of animal vaccines. In finding that APHIS unambiguously expressed its intent to preempt state law, the district court reasoned that the agency both explicitly stated its intent "to occupy the field" and patterned its "no requirements different from or in addition to" language after

other express statutory preemption provisions such as the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. § 1334, the Federal Insecticide, Fungicide & Rodenticide Act, 7 U.S.C. § 136v(b), and the Medical Device Amendments to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 360k(a), which dozens of courts have held preempt common law causes of action falling within the scope of the particular area of law preempted. (Pet. App. at A-32 – A-36)

Second, the district court found that APHIS acted within the scope of its congressionally delegated authority, even though Congress had been silent on the issue of preemption. In finding that APHIS had sufficient authority to preempt state law, the district court pointed to (1) the authority delegated to the agency to promulgate "such rules and regulations as may be necessary" to prevent the manufacture, sale and distribution of any "worthless, contaminated, dangerous or harmful" animal vaccines; (2) the authority delegated to the agency to prevent and eliminate burdens upon and to regulate effectively interstate commerce; and (3) Congress' expressed desire in the legislative history for "uniform national standards" for the manufacture and sale of animal vaccines in the United States. The district court reasoned that the broad authority granted by Congress in VSTA to APHIS compared favorably with other federal programs, most notably the 1934 and 1984 Communications Acts, which this Court has held authorized the FCC to expressly preempt certain areas of state law. Because permitting each of the 50 states through tort law to impose requirements upon animal vaccines different from or in addition to those imposed by APHIS would undermine Congress' call for uniform national standards and the elimination of undue burdens upon commerce, the district court determined that APHIS' declaration of preemption is neither arbitrary, capricious nor manifestly contrary to VSTA. (Pet. App. at A-29 – A-32)

Having determined that APHIS' declaration of preemption was entitled to controlling weight, the district court held that each claim contained in the Amended Complaint was barred. The district court reasoned that each claim, if accepted by a jury, would by necessity impose different or additional requirements upon SBC regarding the safety, efficacy, purity, potency or labeling of the vaccines at issue because it is undisputed that APHIS found the vaccines to have fully satisfied all of its requirements in these areas. (Pet. App. at A-35 – A-37)

Proceedings Before The Seventh Circuit

The United States Court of Appeals for the Seventh Circuit affirmed the district court's decision by applying the same three-part inquiry and relying upon the same reasons as the district court, with one notable addition. Following both the district court's decision and oral argument before the Seventh Circuit, APHIS clarified the scope of its declaration of preemption on December 22, 1995 in response to a congressional inquiry. Both Lynnbrook and SBC asked the Seventh Circuit to take judicial notice of the December 22, 1995 correspondence from Acting Administrator of APHIS, Terry L. Medley, to Senator Wellstone.

The Seventh Circuit granted the motions to take judicial notice of the December 22, 1995 letter from APHIS. The Seventh Circuit agreed with SBC that the correspondence confirmed the interpretation that APHIS intended to include certain state tort claims within the scope of the declaration of preemption:

> Contrary to Lynnbrook's argument that APHIS only intended to preempt positive enactments, the agency included in its preemptive scope additional requirements dictated by States via 'regulations, statutes or other means.' The phrase 'or other means' clearly encompasses state tort claims. Moreover, APHIS' letter signals that state tort claims are available when APHIS

> regulatory standards are violated or discarded. The natural conclusion to draw from this statement is that when APHIS regulations are heeded, state tort claims involving the safety, efficacy, potency, or purity of an animal vaccine do *not* survive. This dichotomy follows from the preemption language chosen by APHIS, as it is precisely when APHIS regulations have been satisfied that a common law action imposes requirements in addition to, or different from, those mandated by APHIS. Where non-compliance is involved, a common law action could simply serve to impose the standards of APHIS. Thus, it is evident that APHIS intended to preempt common law claims relating to areas under its regulatory control (namely the safety, purity, potency and efficacy of vaccines) which would impose additional or different requirements on vaccines, *i.e.*, common law claims involving regulated areas in cases where the manufacturer has complied with all APHIS regulations and standards.

(Pet. App. at A-18 – A-19) (Emphasis in original.)

In response to SBC's motion for taking judicial notice of the December 22, 1995 correspondence, Lynnbrook attempted to raise a belated argument that a genuine issue of material fact existed concerning whether the vaccines at issue complied with APHIS standards. Not only did Lynnbrook fail to adduce any evidence regarding non-compliance at the district court, counsel for Lynnbrook during oral argument at the Seventh Circuit conceded that, if the court were to find that APHIS' declaration covered state tort claims, all of the counts of the Amended Complaint would be preempted – *i.e.*, that Lynnbrook's claims sought to establish requirements "different from or in addition to" those imposed by APHIS regarding the safety, efficacy, purity, potency and labeling of the vaccines at issue. SBC objected to Lynnbrook's

attempt to raise an issue it had waived and the Seventh Circuit stated in its opinion that:

> This is not a case involving non-compliance. Both vaccines have met APHIS standards for safety, purity, potency, and efficacy.

(Pet. App. at A-20) Because all of the claims asserted in the Amended Complaint would impose additional or different requirements in these areas, the Seventh Circuit held that federal law preempted Lynnbrook's claims in their entirety. (Pet. App. at A-20 – A-21)

On April 22, 1996, the Seventh Circuit denied Lynnbrook's petition for rehearing and suggestion for rehearing *en banc*. The Seventh Circuit also denied Lynnbrook's motion to stay issuance of mandate on April 29, 1996.

Following the decision of this Court on June 26, 1996 in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), Lynnbrook filed a motion for the Seventh Circuit to reconsider either its judgment of March 21, 1996, affirming the district court's judgment or its order of April 22, 1996, denying Lynnbrook's petition for rehearing and suggestion for rehearing *en banc*. In its memorandum of law, Lynnbrook argued that this Court's decision in *Lohr* justified reconsideration of this matter, a withdrawal of the Seventh Circuit's judgment and a reversal of the district court's judgment.

On July 8, 1996, after apparently recognizing its procedural error in filing a motion to reconsider, Lynnbrook filed a motion to recall mandate, again asserting that this Court's decision in *Lohr* required the Seventh Circuit to recall mandate. The Seventh Circuit ordered SBC to respond to the motion. In its response, SBC argued that *Lohr* does not call into serious question the correctness of the Seventh Circuit's decision in this case. Upon consideration of the parties' substantive arguments, which included the application of *Lohr* to the facts in this case, the Seventh Circuit denied the motion to recall mandate on August 5, 1996. (Resp. App. at A-31)

REASONS FOR DENYING THE WRIT

Lynnbrook's petition for a Writ of Certiorari should be denied because the question presented is not ripe. At this time, there is no conflict among lower court decisions involving the identical question presented here. In three cases involving the same facts and claims, each court unanimously upheld the validity of APHIS' express declaration of preemption and found that the plaintiffs' claims fall within the scope of the declaration of preemption. The analysis and reasoning applied and the conclusions reached by the courts are the same.

There is also no conflict with relevant decisions of this Court. The Seventh Circuit correctly applied the analyses set forth by this Court for determining the validity of an agency's declaration of preemption and for determining that Lynnbrook's claims fall within the scope of the area of law preempted. In addition, the Seventh Circuit considered and rejected Lynnbrook's arguments that this Court's decision in *Lohr* requires a withdrawal of the Seventh Circuit's judgment and a reversal of the district court's judgment.

Accordingly, there is no reason to remand this case to the Seventh Circuit for reconsideration in light of *Lohr*. Because no court, other than the Seventh Circuit, has considered this issue in light of *Lohr*, it is too early for this Court to consider the question presented. Rather, it would be wiser to allow lower courts to apply *Lohr* to similar cases, allowing the possibility of differing views to emerge and possibly result in a conflict that does not exist at this time. For these reasons, the Court should summarily deny Lynnbrook's petition for a Writ of Certiorari.

I. There Is No Conflict Among Lower Court Decisions Involving The Identical Question Presented Here.

Because the decision of the Seventh Circuit in this case is consistent with final judgments on the same matter entered by other federal and state courts, there is no conflict for this Court to resolve at this time. *See Lynnbrook Farms v. SmithKline Beecham Corp.*, 887 F. Supp. 1100 (C.D. Ill. 1995), *aff'd* 79 F.3d 620 (7th Cir. 1996); *reh'g and suggestion for reh'g en banc denied* (April 22, 1996); Pet. App. at A-1; A-23; *Murphy v. SmithKline Beecham Animal Health Group*, 898 F. Supp. 811 (D. Kan. 1995), *appeal dismissed* (10th Cir. Nov. 14, 1995); *Brandt v. The Marshall Animal Clinic*, 540 N.W.2d 870 (Minn. Ct. App. 1995), *review denied* (Minn. Feb. 9, 1996). In denying petitions for a Writ of Certiorari, this Court has repeatedly cited a lack of conflict among lower courts as a reason to wait for an issue to receive further study before it is addressed by this Court:

> My vote to deny certiorari in these cases does not reflect disagreement with Justice Marshall's appraisal of the importance of the underlying issue. . . . I believe that further consideration of the substantive and procedural ramifications of the problem by other courts will enable us to deal with the issue more wisely at a later date. There is presently no conflict of decision within the federal system. . . . In my judgment it is a sound exercise of discretion for the Court to allow the various States to serve as laboratories in which the issue receives further study before it is addressed by this Court. *McCray v. New York*, 461 U.S. 961 (1983).
>
> [T]here is no allegation in the petition for certiorari that there is a conflict between the decision of the Court of Appeals in this case and any other Federal Court of Appeals decision. Often the law develops in a more satisfactory fashion if this court withholds review of novel issues

> before differing views have been expressed by other federal courts. *Vasquez v. United States*, 454 U.S. 975 (1981).
>
> Petitions may have been denied because, even though serious constitutional questions were raised, it seemed to at least six members of the Court that the issue was either not ripe enough or too moribund for adjudication; that the question had better await the perspective of time or that time would soon bury the question or, for one reason or another, it was desirable to wait and see . . . *Darr v. Burfurd*, 339 U.S. 200 (1949).
>
> It may be desirable to have different aspects of an issue further illuminated by the lower courts. Wise adjudication has its own time for ripening. *Maryland v. Baltimore Radio Show*, 338 U.S. 912 (1949).

These judicial policy considerations militate in favor of a denial of certiorari in this case where there is no conflict among any of the decisions of lower federal and state courts regarding the same facts and question presented here.

Lynnbrook Farms, Murphy and *Brandt* involved essentially identical factual allegations and claims.[1] The plaintiffs alleged that their cattle suffered harm purportedly caused by vaccines manufactured by SBC. (Pet. App. at A-2; A-25; 898 F. Supp. at 813; 540 N.W.2d at 873) Plaintiffs contended that the vaccines either failed to protect against the diseases they were designed to counteract or were unsafe. (*Id.*) Plaintiffs asserted a variety of state law

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[1] In fact, counsel for Lynnbrook also represented the plaintiffs in *Murphy* and *Brandt*. The allegations contained in the Complaints in all three cases are virtually identical except for the names of the plaintiffs and the names of the vaccines at issue.

claims sounding in strict liability, negligence, misrepresentation, false advertising, and breach of implied warranties of merchantability and fitness. (Pet. App. at A-3; A-25; 898 F. Supp. at 813; 540 N.W.2d at 873) In all three cases, SBC submitted uncontroverted evidence that the vaccines at issue complied with APHIS' requirements for safety, efficacy, purity, potency and labeling. (Pet. App. at A-20; A-36; 540 N.W.2d at 875 n.3)

The courts in *Lynnbrook Farms, Murphy* and *Brandt* unanimously upheld the validity of APHIS' express declaration of preemption and found that each of the plaintiffs' claims fall within the scope of the declaration of preemption. (Pet. App. at A-20; A-36; 898 F. Supp. at 817-18; 540 N.W.2d at 878) The courts not only reached the same conclusions, they followed the same analysis and applied the same reasoning.[2]

First, each of the courts acknowledged the principle first announced by this Court in *United States v. Shimer*, 367 U.S. 374 (1961), and confirmed in *Fidelity Fed. Savings & Loan Ass'n v. de la Cuesta*, 458 U.S. 141 (1982), and *City of New York v. Federal Comm'n*, 486 U.S. 57 (1988), that a federal agency may expressly preempt state law even without express congressional authorization to do so. (Pet. App. at A-4 – A-6; A-28; 898 F. Supp. at 814-15; 540 N.W.2d at 874-76) To determine whether APHIS' declaration of preemption was valid, the courts applied the analysis set forth by this Court in *Shimer, Fidelity* and *City*

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[2] Lynnbrook's argument that this Court should exercise its supervisory powers because the Seventh Circuit purportedly departed from the accepted and usual course of judicial proceedings and sanctioned such a departure by a lower court, (Pet. App. 19-20), is of no moment because it is based solely upon (1) cases decided *before* both the August 27, 1992 declaration of preemption by APHIS and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); (2) cases in which the preemption defense was not asserted; and (3) cases in which the court wrote no opinion.

of New York. Accordingly, the courts asked: (1) whether the agency acted within the scope of its delegated authority; and (2) whether the agency clearly expressed its intent to preempt state law, including common law damages actions. (Pet. App. at A-6; A-29; 898 F. Supp. at 814-15; 540 N.W.2d at 874-76)

In concluding that APHIS acted within the scope of its delegated authority, each of the courts compared the authority delegated by Congress in VSTA to APHIS, to the language construed by this Court in *Shimer, Fidelity* and *City of New York* as empowering the agencies in those cases to preempt state law. The *Lynnbrook Farms, Murphy* and *Brandt* courts reasoned that the authority delegated to APHIS in the language of the statute and the legislative history was broad enough to permit APHIS to preempt state law. (Pet. App. at A-6 – A-13; A-29 – A-35; 898 F. Supp. at 814-15; 540 N.W.2d at 874-76)

As to APHIS' intent to preempt all state law, including common law damages actions, the *Lynnbrook Farms, Murphy* and *Brandt* courts reasoned that the agency used certain "magic" words – *i.e.*, stating its intent "to occupy the field" and its intent to preempt state "requirements different from or in addition to" those imposed by the agency – which dozens of courts have held preempt common law causes of action falling within the scope of the particular area of law preempted. (Pet. App. at A-13 – A-19; A-32 – A-35; 898 F. Supp. at 815-17; 540 N.W.2d at 876-78)

The district court in this case and the *Murphy* and *Brandt* courts did not have the benefit of reviewing the December 22, 1995 correspondence from Acting Administrator of APHIS, Terry L. Medley, to Senator Wellstone, which confirms the scope of APHIS' declaration of preemption. However, the Seventh Circuit stated that "although the case law supporting our conclusion is substantial, we are even more confident that APHIS intended to include common law damages actions within the scope of its preemption after reviewing the only official APHIS

statement (to our knowledge) explaining its intent in adopting the quoted regulation." (Pet. App. A-17) As set forth above, that correspondence confirmed that APHIS' intent was to preempt *all* state law whether "by statute, regulations *or other means.*" (Resp. App. A-29 – A-30) (Emphasis added.)

Having found that APHIS clearly expressed its intent to preempt state law, and having found that APHIS neither exceeded its statutory authority nor acted arbitrarily, capriciously or manifestly contrary to the statute, the *Lynnbrook Farms, Murphy* and *Brandt* courts applied the analysis set forth by this Court in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) to determine whether plaintiffs' claims fall within the scope of the declaration of preemption. (Pet. App. at A-20 – A-21; A-35 – A-37; 898 F. Supp. at 817-18; 540 N.W.2d at 878) In all three cases it was undisputed that APHIS had licensed each of the vaccines, and that through the licensure and post-licensure review processes, the agency necessarily determined that the vaccines satisfied all of its requirements. The courts unanimously held that each of the plaintiffs' claims, if accepted by a jury, would impose a requirement different from or in addition to APHIS' requirements regarding the safety, efficacy, purity, potency or labeling of the animal vaccines at issue. (*Id.*)

Because there is no conflict among the lower court decisions either in the analysis and reasoning they applied or the conclusions they reached, it would be unwise for this Court to address at this time the question presented by Lynnbrook. As in past cases, this Court should withhold review until the issue receives further study in lower courts where differing views may be expressed and illuminated.

II. There Is No Conflict With Relevant Decisions Of This Court.

Because the Seventh Circuit correctly applied the relevant decisions of this Court, Lynnbrook's petition for a Writ of Certiorari should be denied. As indicated above, the Seventh Circuit correctly applied the analysis set forth by this Court in *Shimer, Fidelity* and *City of New York* for determining the validity of APHIS' declaration of preemption. The Seventh Circuit also correctly applied the *Cipollone* analysis in determining that Lynnbrook's claims fall within the scope of APHIS' declaration of preemption.

In addition, the Seventh Circuit considered Lynnbrook's arguments that this Court's decision in *Lohr* requires a withdrawal of the Seventh Circuit's judgment and a reversal of the district court's judgment. Upon consideration of substantive arguments based upon *Lohr*, the Seventh Circuit correctly denied Lynnbrook's motion to recall mandate.

A. This Court in *Lohr* Explicitly Confirmed That The Term "Requirement" Contained In The MDA Preemption Clause Includes State Court Claims.

Lynnbrook's Argument IA, (Pet. App. at 8-12), is based upon its belief that this Court in *Lohr* held that the term "requirement" found in the MDA preemption clause does not encompass state common law damages actions. *This Court made no such holding*. Entirely to the contrary, five Justices *explicitly confirmed* this Court's holding in *Cipollone* that the term "requirements" *does* encompass state tort actions for damages. Speaking on behalf of herself, Chief Justice Rehnquist, and Justices Scalia and Thomas, Justice O'Connor concluded that 21 U.S.C. § 360k(a) preempts both state statutes and regulations *and* state common law actions falling within its scope:

> Whether relating to the labeling of cigarettes or the manufacture of medical devices, state common-law damages actions operate to require manufacturers to comply with common-law duties. *As Cipollone declared, in answer to the same argument raised here that common-law actions do not impose requirements, "such an analysis is at odds both with the plain words" of the statute and "with the general understanding of common-law damages actions."* [Citation omitted.] *If § 360k's language is given its ordinary meaning, it clearly pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA – just as it would pre-empt a state statute or regulation that had that effect. Justice BREYER reaches the same conclusion.*

116 S. Ct. at 2262-63 (emphasis added). In his concurring opinion, Justice Breyer expressly agreed:

> . . . [T]he MDA will sometimes pre-empt a state-law tort suit. I basically agree with Justice O'CONNOR's discussion of this point and with her conclusion. [Citation omitted.] The statute's language, read literally, supports that conclusion. . . . *One can reasonably read the word "requirement" as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law.*
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> * * *
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> Consequently, I believe that ordinarily, *insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.* It is possible that the plurality also agrees on this point, although it does not say so explicitly.

116 S. Ct. at 2259 (emphasis added). Thus, *Lohr* confirms that this Court continues to hold that the term "requirements" *includes* state tort claims.[3]

Moreover, in light of the weight accorded by the majority in *Lohr* to the FDA's preemptive intent, APHIS' express confirmation that the decisions of the district court in this case and the courts in *Murphy* and *Brandt* correctly reflect the scope of its preemptive intent is highly significant. In *Lohr*, the Supreme Court was confronted, in net effect, with *two* different preemption clauses – 21 U.S.C. § 360k(a),[4] authored by Congress, and 21 C.F.R. § 808.1(d),[5] authored by the FDA. In giving

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[3] Lynnbrook's argument that the word "requirement" in the MDA preemption clause does not encompass state tort claims stems from language contained in Part IV of Justice Stevens' plurality opinion. Lynnbrook ignores the fact that Justice Breyer expressly *declined* to join Part IV of Justice Stevens' opinion. *See* 116 S. Ct. at 2261-62. With few exceptions, Lynnbrook's citations to *Lohr* in its petition are taken from Part IV of Justice Stevens' opinion. (Pet. at 9, 10, 11, 12, 13, 14, 15.) Because only four Justices subscribed to Part IV of the plurality opinion, Lynnbrook is repeatedly mistaken in arguing that the expressions of Justice Stevens found in Part IV represent this Court's official holding.

[4] 21 U.S.C. § 360k(a) provides in pertinent part:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in the requirement applicable to the device under [the MDA].

[5] 21 C.F.R. § 808.1(d) provides in pertinent part:

> State or local requirements are preempted only when the Food and Drug Administration has established

controlling weight to the *FDA's interpretation* of 21 U.S.C. § 360k(a) and *not* the plain language of the statute itself, Justices Stevens and Breyer both emphasized the FDA's administrative expertise and informed judgment to ascertain the proper effect of its regulations upon state law. As Justice Stevens stated:

> Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the [MDA], *the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), *and therefore, whether it should be pre-empted*. For example, Congress explicitly delegated to the FDA the authority to exempt state regulations from the pre-emptive effect of the MDA – *an authority that necessarily*

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specific counterpart regulations or there are other specific requirements applicable to a particular device under the [MDA], thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of [21 U.S.C. § 360k(a)]. The following are examples of State or local requirements that are not regarded as preempted by [21 U.S.C. § 360k(a)]:

(1) *Section [360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices* (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. (Emphasis added.)

> *requires the FDA to assess the pre-emptive effect that the act and its own regulations will have on state laws. See* § 360k(b). . . . *The ambiguity in the statute – and the Congressional grant of authority to the agency on the matter contained within – provide a "sound basis" . . . for giving substantial weight to the agency's view of the statute.* See *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *Hillsborough Cty. [v. Automated Medical Laboratories, Inc.]*, 471 U.S. [707] at 714 (considering FDA understanding of pre-emptive effect of its regulations "dispositive").

116 S. Ct. at 2255-56 (emphasis added). Justice Breyer agreed:

> [T]his court has previously suggested that, in the absence of a clear Congressional demand as to preemption, *courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect.* See *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 721 (1985); cf. *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. ___, ___ (1996) (*slip op.*, at 3-5); *Lawrence County v. Lead-Deadwood School Dist. No. 40-1*, 469 U.S. 256, 261-262 (1985); *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-845 (1984). To draw a similar inference here makes sense, and not simply because of the statutory ambiguity. *The [FDA] is fully responsible for administering the MDA. [Citation omitted.] That responsibility means informed agency involvement and, therefore, special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives. See Hillsborough*, 471 U.S. at 721. The FDA can translate these understandings into

> particularized pre-emptive intentions accompanying its various rules and regulations. See *id.*, at 718.
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> * * *
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> *It therefore seems to me that the better indicator of the FDA's intent is its pre-emption-related regulation. And that regulation's word "specific" would seem a reasonable exercise of the leeway that statutory language and practical administrative circumstance suggest Congress intended to grant to the agency.*

116 S. Ct. at 2260 (emphasis added).

Read properly, *Lohr* vividly illustrates the degree of deference to be given to a federal agency's authorized declaration of preemption. So long as a federal agency acts within the scope of the authority granted to it by Congress,[6] the agency's expressed preemptive intent will prevail even over ambiguous Congressional declarations falling within the same area, in light of the agency's superior "informed involvement" and "special understanding" of the impact of its preemptive intent upon state law.

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[6] On pages 17-18 of its petition, Lynnbrook offers a new argument – that APHIS' declaration of preemption is manifestly contrary to 21 U.S.C. § 151, and therefore, is beyond the scope of authority granted to APHIS by Congress. Having never before asserted this argument, Lynnbrook has waived it. Furthermore, this argument is completely unrelated to this Court's holding in *Lohr*. Finally, the argument is incorrect. Congress delegated to APHIS the authority to determine which vaccines are not "worthless, contaminated, dangerous or harmful." APHIS has specified that vaccines which satisfy its standards for safety, efficacy, potency, purity and labeling are *not* "worthless, contaminated, dangerous or harmful." That declaration is entitled to controlling weight by this Court. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 845 (1984).

As the Seventh Circuit correctly noted, when APHIS issued its declaration of preemption in August, 1992, APHIS patterned its language after other Congressional declarations of preemption, which according to this Court in *Cipollone*, had the effect of preempting *both* state positive enactments *and* state tort actions falling within their scope. More importantly, APHIS' December 22, 1995 correspondence confirms the agency's intent to preempt *all* state law, including the claims at issue in *Brandt, Murphy*, and this case, which sought to impose requirements different from or in addition to those imposed by APHIS regarding the safety, efficacy, purity, potency and labeling of the vaccines at issue.

Thus, the Seventh Circuit followed the command of *Lohr*, to the letter: it correctly construed APHIS' use of the term "requirements" in its declaration of preemption as encompassing state tort actions; it correctly ascertained the scope of APHIS' preemptive intent, as manifested by its declaration of preemption and its December 22, 1995 correspondence to Senator Wellstone; it afforded controlling weight to APHIS' expressed preemptive intent; and, it examined the claims asserted by Lynnbrook to determine whether or not they fall within the area intended by APHIS to be preempted. The fact that the FDA intended a *different* preemptive effect for claims arising under the MDA's preemption clause, as illustrated by 21 C.F.R. § 808.1(d), is of no moment.

B. Significant Policy Differences Between VSTA And The MDA Explain Why APHIS Intends A Broader Preemptive Effect Than That Provided By The FDA For The MDA.

Lynnbrook's argument that the MDA and VSTA serve similar purposes and therefore, the Seventh Circuit's decision conflicts with this Court's decision in *Lohr*, (Pet. App. at 13-15), fails for a number of reasons. First, this argument is based upon Part IV of the Opinion which did

not command a majority of the Justices. Second, an analysis of the purpose and history of the statute is unnecessary where, as here, APHIS unambiguously expressed its intent to preempt all state law including common law damages actions. Nonetheless, even if such an analysis is undertaken, VSTA warrants and APHIS intends a broader preemptive effect than that provided by the FDA for the MDA.

The likely reason why APHIS intends a broader preemptive effect than that provided by the FDA in 21 C.F.R. § 808.1(d) can be found in the different missions of the two agencies, the different statutes they must implement, and fundamental differences in the products and industries they regulate. Animal vaccines, for instance, promote the health of animals which produce food for all Americans – *e.g.*, dairy cattle (milk, butter, cheese and beef), beef cattle (meat), poultry (meat and eggs), and swine (meat). When used, animal vaccines can substantially enhance the health of these animals, to the benefit of not just the individual animal owner, but the quantity, quality, and affordability of the nation's food supply.

Encouraging animal producers to *use* these vaccines is an important part of APHIS' mission. As the legislative history to the 1985 amendments to the VSTA indicates, Congress sought to promote not just the safety and efficacy of animal vaccines, but also their *availability* via national, uniform standards and the elimination of burdens upon commerce. APHIS could reasonably conclude, based upon its expertise and knowledge of the market, that imposing tort liability upon manufacturers of animal vaccines which have fully satisfied all of APHIS' standards: (1) does little to further enhance the safety and efficacy of animal vaccines which have already undergone APHIS' thorough pre-licensure approval process; (2) subjects vaccine manufacturers to additional burdens and costs, causing vaccine prices to increase and even forcing some manufacturers out of business altogether; and, (3) diminishes animal producers' incentive to use animal

vaccines (since agriculture prices are determined by national markets and bear no relation to an individual farmer's cost of production, which in turn renders animal producers unable to recover their increased vaccine costs) – thereby threatening the quality, quantity and affordability of the nation's food supply.

By contrast, the FDA's mission with respect to human medical devices is quite different. As the Supreme Court noted in *Lohr*, most medical devices sold in this country are so-called "substantial equivalent" devices permitted by § 510(k) of the MDA which, unlike animal vaccines, undergo little agency scrutiny. 116 S. Ct. at 2247-49. Furthermore, the FDA has *not* been charged by Congress with eliminating and minimizing burdens upon commerce in order to insure that medical devices are available at a reasonable cost to consumers. Users of medical devices are typically driven in their decision-making not by the cost of the device, but by their personal health needs and the availability of health insurance, private or public. Finally, the benefits of medical devices are essentially confined to the health of the specific individuals for whom they are prescribed; a consumer's choice to use or not use a given medical device carries few if any implications for society as a whole. Because substantial policy differences exist between the purposes of VSTA and the MDA, there is no conflict between this Court's decision in *Lohr* and the Seventh Circuit's decision in this case.

C. *Lohr* Cannot Resurrect Any Claims Lynnbrook Waived For Noncompliance With Federal Standards.

Lynnbrook's attempt to resurrect a belated claim for noncompliance with federal standards based upon this Court's holding in *Lohr* must fail. (*See* Pet. App. 15-17) SBC agrees that the question of compliance with APHIS standards has always been a material fact in this case and an essential part of SBC's preemption defense. The uncontroverted evidence accompanying SBC's motion for

summary judgment demonstrates that its vaccines *did* satisfy all applicable federal requirements. To demonstrate that Lynnbrook's claims were ones which, if accepted by a jury, would impose "different or additional" requirements, SBC adduced the material fact that SBC's vaccines fully complied with all applicable APHIS standards. With that fact established, the only way a jury could find the vaccines to be unsafe, inefficacious or improperly labeled – the essential allegations of the Amended Complaint – was by imposing standards "different from or in addition to" APHIS' requirements.

To establish this fact, SBC submitted in support of its motion for summary judgment the Affidavit of Cyril G. Gay, D.V.M., Ph.D., which in pertinent part provided:

> Each of the SBC vaccines involved in this litigation, through the licensure process and through post-licensure testing and evaluation, has been determined by APHIS to satisfy all requirements for purity, safety, potency and efficacy contained in the APHIS standards. Each has been designed, manufactured and tested pursuant to APHIS standards, and of necessity APHIS approved the content and sufficiency of all design, manufacturing and testing data submitted prior to licensure of each vaccine. In addition, the text, layout and design of all labeling on these vaccines, including the packaging and product inserts, have been specifically approved in writing by APHIS.

(Resp. App. at A-17 – A-24)[7]

Lynnbrook, of course, could have opposed SBC's motion for summary judgment on the grounds that material facts were at issue, *i.e.*, that evidence existed showing

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[7] Lynnbrook failed to disclose to this Court that SBC submitted uncontroverted evidence of compliance with APHIS standards through the testimony of Dr. Gay.

that the vaccines somehow did not meet APHIS' standards. To do that, appellant was obligated to introduce affirmative evidence negating the facts recited in Dr. Gay's Affidavit. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1282-83 (7th Cir. 1995); *see also* Rule 2.9 of the General Rules of the United States District Court for the Central District of Illinois.

Lynnbrook did not do so.[8] No "Statement of Genuine Issues" setting forth any disputed facts appeared in Lynnbrook's brief in opposition to SBC's motion for summary judgment. Lynnbrook neither submitted any affidavits or other evidence in opposition to SBC's motion for summary judgment, nor availed itself of Rule 56(f) of the Federal Rules of Civil Procedure to take discovery on any material factual issue. To the contrary, appellant stipulated below that *no* discovery was required to adjudicate the preemption issue. (Resp. App. A-26 – A-28) Furthermore, Lynnbrook argued both before the district court and the Seventh Circuit that compliance with APHIS' requirements was neither dispositive nor a defense to liability because the requirements were intended only to be "minimum standards." Finally, Lynnbrook's counsel

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[8] Notably, the primary vaccine at issue in this case – *CattleMaster 4 – was also the primary vaccine involved in *Brandt*. Counsel for Lynnbrook in this case also represented the plaintiffs in *Brandt*. Unlike this case, the preemption motion in *Brandt* was not brought until essentially all discovery was completed. Yet, as the Minnesota Court of Appeals observed in *Brandt*, there was no evidence, nor even any claim, in that case that the *CattleMaster 4 vaccine failed to comply with applicable APHIS standards. 540 N.W.2d at 875, n. 3. Thus, it is hardly surprising that Lynnbrook has never claimed, until this Court's decision in *Lohr*, that SBC's vaccines failed to meet APHIS' standards.

conceded during oral argument before the Seventh Circuit that, if the Court were to find that APHIS' declaration covered state tort claims, all of the counts of the Amended Complaint would be preempted – *i.e.*, that Lynnbrook's claims sought to establish requirements "different from or in addition to" those imposed by APHIS regarding the safety, efficacy, purity, potency and labeling of SBC's vaccines.

To summarize, there has never been, and is not now, any issue in this case that SBC's vaccines somehow failed to comply with APHIS' licensing requirements. Dr. Gay's uncontroverted Affidavit conclusively establishes that SBC's vaccines satisfied all of APHIS' requirements. This case never has been, and cannot be, one for noncompliance with APHIS' regulatory standards. Although Lynnbrook attempted to resurrect this argument at the Seventh Circuit following this Court's decision in *Lohr*, the Seventh Circuit observed that "it is undisputed the SBC manufactured and marketed *CattleMaster 4 and Ultrabac 7/Somubac according to all APHIS regulations. This is not a case involving non-compliance." (Pet. App. at A-20)

Lohr in no way calls this portion of the Seventh Circuit's holding in question. Even before *Lohr*, APHIS stated that it did not intend to preempt state tort actions arising from non-compliance with APHIS' regulatory standards. (Resp. App. at A-29) Thus, *Lohr* adds nothing new to the debate.

Because the Seventh Circuit's decision is consistent with the relevant decisions of this Court, Lynnbrook's petition should be denied. This Court should not remand the case to the Seventh Circuit to be reconsidered in light of *Lohr*, because as indicated above, the parties briefed all of the substantive arguments based upon *Lohr* to the Seventh Circuit when Lynnbrook asked the court to recall mandate. The Seventh Circuit considered those arguments and denied the motion. (Resp. App. at A-31) Finally, the application of *Lohr* to APHIS' declaration of

preemption is not a question this Court should decide at this time. The Seventh Circuit is the *only* court to have considered this issue. Allowing other courts to consider the question presented by this case in light of *Lohr* could lead to the expression of differing views and a conflict which does not exist at this time. Given this Court's limited judicial resources, it would make better sense to decide this question after the issue has had a chance to ripen. Accordingly, this Court should summarily deny Lynnbrook's petition for a Writ of Certiorari.

CONCLUSION

For the reasons stated above, the petition for a Writ of Certiorari should be denied.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
PEORIA DIVISION

LYNNBROOK FARMS, an Illinois General Partnership, Plaintiff, vs. SMITHKLINE BEECHAM CORPORATION, and NORDEN LABORATORIES, INC., Defendants.	CASE NO. 94-CV-1227 AMENDED COMPLAINT and DEMAND FOR JURY TRIAL

Plaintiff, LYNNBROOK FARMS, for its cause of action, alleges as follows:

GENERAL ALLEGATIONS

1. Plaintiff, LYNNBROOK FARMS, located at Williamsfield, Knox County, Illinois, is a General Partnership organized under the laws of the State of Illinois, and its partners are as follows, to-wit: Lester Brooks Potts, Jr., who resides at Williamsfield, Knox County, Illinois; Robert Lynn Potts, who resides at Dahinda, Knox County, Illinois; Mary Diane Potts, who resides at Williamsfield, Knox County, Illinois; and Gayla Marie Potts, who resides at Dahinda, Knox County, Illinois.

2. Defendant, SMITHKLINE BEECHAM CORPORATION, is and was at all times material hereto a corporation incorporated under the laws of the State of

Pennsylvania having its principal place of business in a State other than the State of Illinois.

3. Defendant, NORDEN LABORATORIES, INC., was at all times material hereto a corporation incorporated under the laws of the State of Delaware having its principal place of business in a State other than the State of Illinois.

4. The matter in controversy exceeds, exclusive of interest and costs, the sum of Fifty Thousand Dollars ($50,000.00).

5. At all relevant times, Plaintiff was engaged in the business of raising and selling cattle.

6. Defendant, SMITHKLINE BEECHAM CORPORATION, is and was at all times material hereto a corporation duly authorized to transact business in the State of Illinois.

7. Defendant, SMITHKLINE BEECHAMN CORPORATION, a Pennsylvania Corporation, may have become the successor in interest to Defendant, NORDEN LABORATORIES, INC., including the claims set out herein, as the result of a 1990 joint venture with Defendant, NORDEN LABORATORIES, INC.

8. Defendant, SMITHKLINE BEECHAM CORPORATION, a Pennsylvania Corporation, may have become the successor in interest to Defendant, NORDEN LABORATORIES, INC., including the claims set out herein, as the result of a 1992 merger with Defendant, NORDEN LABORATORIES, INC.

9. SMITHKLINE BEECHAM CORPORATION and NORDEN LABORATORIES, INC. are hereinafter collectively referred to as "Defendants".

COUNT I – STRICT LIABILITY

10. Plaintiff incorporates into this Count I all the allegations of paragraphs 1 through 9 of its General Allegations as though fully set forth herein.

11. At all times material hereto, the Defendants were engaged in the business of manufacturing a variety of animal vaccines which were sold in the State of Illinois to various persons and firms for distribution to the general public, as ultimate consumers, and promoted by sales representatives in the State of Illinois.

12. Among the animal vaccines formulated, compounded, manufactured, tested, marketed and recommended by Defendants for use with cattle is their product known as "*CattleMaster4".

13. While engaged in the manufacture and sale of animal vaccines, the Defendants sold *CattleMaster4 vaccine to, among others, The Miller Company, Inc., located in Morton, Tazewell County, Illinois.

14. Defendants expected the vaccine sold to The Miller Company to reach consumers in the condition in which it was sold.

15. During or about May, 1992, Plaintiff purchased from The Miller Company the vaccine, *CattleMaster4, which is the product of Defendants for vaccination of its cattle. The objective of the vaccinations was to aid in the prevention of debilitating or mortal infections and diseases.

16. During or about May, 1992, the said vaccine was shipped refrigerated to Plaintiff via United Parcel Service.

17. The vaccine, *CattleMaster4, was kept refrigerated upon receipt by Plaintiff.

18. During or about June, 1992, Plaintiff vaccinated its cattle with the aforesaid vaccine which was in the same condition in which it was supplied to Plaintiff and The Miller Company.

19. At the time of vaccinating its cattle with Defendants' product, Plaintiff used the vaccine in accordance with the instructions and according to the appropriate business custom.

20. Plaintiff, at the time of the aforesaid use of *CattleMaster4, intended the vaccine to aid in the prevention of bovine viral diarrhea, bovine respiratory syncytial virus, infectious rhinotracheitis virus, and parainfluenza in healthy animals, and was unaware of any defect or dangerous condition in the vaccine and expected the vaccine to be safe for use in a foreseeable manner.

21. Notwithstanding the inoculation of Plaintiff's cattle with the Defendants' product, Plaintiff's cattle, after the said injections of mid 1992 were administered, contracted debilitating and mortal infections and diseases which killed certain of Plaintiff's animals or so debilitated certain others as to make it necessary for Plaintiff to sell or dispose of them at a loss.

WHEREFORE, Plaintiff PRAYS for a Judgment jointly and severally against Defendants on Count I for an amount in excess of $50,000, plus interest thereon at the

highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT II – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE UNDER THE ILLINOIS UNIFORM COMMERCIAL CODE (810 ILCS 5/1-101 ET SEQ.)

22. Plaintiff incorporates into this Count II all the allegations of paragraphs 1 through 21 of its General Allegations and its First Count as though fully set forth herein.

23. By the sale of the vaccine known as *CattleMaster4, the Defendants impliedly warranted, within the meaning of the Illinois Uniform Commercial Code, 810 ILCS 5/1-101 et seq., that such vaccine was fit and suitable for the purposes for which it was manufactured and that it was safe when used in a foreseeable manner for inoculating cattle to aid in preventing bovine viral diarrhea, bovine respiratory syncytial virus, infectious rhinotracheitis virus, and parainfluenza in healthy cattle.

24. At the time of contracting to sell said vaccine to Plaintiff, Defendants had reason to know of the particular purpose for which Plaintiff required said vaccine, specifically, to prevent bovine viral diarrhea, bovine respiratory syncytial virus, infectious rhinotracheitis virus, and parainfluenza in healthy cattle.

25. In purchasing and using the vaccine, Plaintiff relied on Defendants and their expertise and judgment in

the area of manufacturing and marketing animal vaccines.

26. The vaccine was not fit for the purpose intended in that it did not aid in preventing bovine viral diarrhea, bovine respiratory syncytial virus, infectious rhinotracheitis virus, and parainfluenza in healthy cattle.

27. As a proximate result of the Defendants' breach of warranty of fitness for a particular purpose, Plaintiff sustained damages in the manner previously alleged.

WHEREFORE, Plaintiff PRAYS for a Judgment jointly and severally against Defendants on Count II for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT III – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY UNDER THE ILLINOIS UNIFORM COMMERCIAL CODE (810 ILCS 5/1-101, ET SEQ.)

28. Plaintiff incorporates into this Count III the allegations of paragraphs 1 through 27 of the General Allegations and the First and Second Counts as though fully set forth herein.

29. Defendants, through their agents, possessed special knowledge, skill and expertise concerning the formulation, compounding, testing, manufacturing, labeling, marketing, selection and use of medications and vaccines for animals, including cattle of the kind produced by Plaintiff, and were therefore "merchants" for

purposes of the Illinois Uniform Commercial Code, 810 ILCS 5/1-101 et seq.

30. Defendants impliedly warranted that their *CattleMaster4 product was of merchantable quality with respect to goods of their kind in that they would pass without objection in the trade, aid in the prevention of debilitating or moral infections and diseases, and provide an effective, safe, viable and successful inoculate.

31. The vaccine failed to protect Plaintiff's cattle from debilitating or mortal infections and diseases, including bovine viral diarrhea, bovine respiratory syncytial virus, infectious rhinotracheitis virus, and parainfluenza.

32. As a consequence of the failure of *CattleMaster4 to prevent the foregoing diseases, said vaccine was unfit for its ordinary purpose and would not pass without objection in the trade, and was thus unmerchantable at the time of sale.

33. As a direct, proximate result of the breach of the implied warranty or warranties by Defendants with respect to their product, Plaintiff has sustained damages as previously alleged.

WHEREFORE, Plaintiff PRAYS for Judgment jointly and severally against Defendants on Count III of its Complaint for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus attorneys fees, plus costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT IV – FRAUDULENT MISREPRESENTATION

34. Plaintiff incorporates into this Count IV the allegations of paragraphs 1 through 33 of the General Allegations and the First, Second and Third Counts as though fully set forth herein.

35. Defendants, acting through their officers, agents, servants, representatives, or employees, supplied false information through advertising and promotion of the *CattleMaster4 vaccine by stating and claiming that said vaccine was effective and safe when used in a foreseeable manner.

36. Said representations were made as a statement of fact and were false when made.

37. Said representations were made by Defendants and their agents with knowledge of their falsity or with reckless disregard for the truth thereof and a willful and wanton disregard for the truth and the rights of the Plaintiff.

38. Defendants made said representations with the intention of inducing Plaintiff to act upon said statements.

39. In reliance on the truth of such misrepresentations, Plaintiff purchased *CattleMaster4 from The Miller Company and used the same in the manner and for the purpose as advertised and promoted by Defendants.

40. As a proximate result of Plaintiff's reliance upon Defendants' statements, Plaintiff has sustained damages in the manner previously alleged.

WHEREFORE, Plaintiff PRAYS for Judgment jointly and severally against Defendants on Count IV of its Complaint for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT V – ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT (815 ILCS 505/1 ET SEQ.)

41. Plaintiff incorporates into this Count V the allegations of paragraphs 1 through 40 of the General Allegations and the First, Second, Third and Fourth Counts as though fully set forth herein.

42. At all times material hereto, Plaintiff was a "person" for purposes of the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 et seq.

43. At all times material hereto, Plaintiff was a "consumer" for purposes of the Illinois Consumer Fraud and Deceptive Business Practices Act.

44. At all times material hereto, Defendants were engaged in "trade" or "commerce" for purposes of the Illinois Consumer Fraud and Deceptive Business Practices Act.

45. In violation of Section 2 of the Illinois Consumer Fraud and Deceptive Business Practices Act, Defendants, acting through their officers, agents, employees, servants, or representatives, employed deception, fraud, false pretense, false promise, misrepresentation, and concealment,

suppression, or omission of material fact in that they supplied false information through their advertising and promotion of the *CattleMaster4 vaccine by stating and claiming that said vaccine was effective and safe when used in a foreseeable manner.

46. Said representations were made as statements of material fact and were false when made.

47. Said representations were made by Defendants and their agents with knowledge of their falsity or with reckless disregard for the truth thereof and a willful and wanton disregard for the truth and the rights of the Plaintiff.

48. Defendants made said representations with the intention of inducing Plaintiff to act upon said statements.

49. In reasonable reliance on the truth of such misrepresentations, Plaintiff purchased *CattleMaster4 from The Miller Company and used the same in the manner and for the purpose as advertised and promoted by Defendants.

50. As a proximate result of Plaintiff's reliance upon Defendants' statements, Plaintiff was damaged in the manner previously alleged.

WHEREFORE, Plaintiff PRAYS for Judgment jointly and severally against Defendants on Count V of its Complaint for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT VI – FAILURE TO WARN (STRICT LIABILITY)

51. Plaintiff incorporates into this Count VI the allegations of paragraphs 1 through 50 of the General Allegations and the First, Second, Third, Fourth and Fifth Counts as though fully set forth herein.

52. The *CattleMaster4 vaccine sold to Plaintiff by Defendants was unreasonably dangerous and in a defective condition because the said vaccine was not accompanied by an adequate warning that would have allowed Plaintiff to use the product without injury to its cattle. The warning accompanying the product was inadequate in that it failed to advise Plaintiff that use of said product in conjunction with other products could cause a dangerous immunosuppressive reaction in the cattle, resulting in the illness and/or death of the cattle.

53. As a result of the defective and unreasonably dangerous condition of the *CattleMaster4 vaccine, Plaintiff incurred damage in the manner previously alleged.

WHEREFORE, Plaintiff PRAYS for Judgment jointly and severally against Defendants on Count VI of its Complaint for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT VII – STRICT LIABILITY

54. Plaintiff incorporates into this Count VII the allegations of paragraphs 1 through 53 of the General Allegations and the First, Second, Third, Fourth, Fifth and Sixth Counts as though fully set forth herein.

55. At all times material hereto, the Defendant, SMITHKLINE BEECHAM CORPORATION, was engaged in the business of manufacturing a variety of animal vaccines which were sold in the State of Illinois to various persons and firms for distribution to the general public, as ultimate consumers, and promoted by sales representatives in the State of Illinois.

56. Among the animal vaccines formulated, compounded, manufactured, tested, marketed and recommended by Defendant, SMITHKLINE BEECHAM CORPORATION, for use with cattle is its product known as Ultrabac7/Somubac.

57. While engaged in the manufacture and sale of animal vaccines, the Defendant, SMITHKLINE BEECHAM CORPORAITON, sold Ultrabac7/Somubac vaccine to, among others, The Miller Company, Inc., located in Morton, Tazewell County, Illinois.

58. Defendant, SMITHKLINE BEECHAM CORPORATION, expected the said vaccine sold to The Miller Company to reach consumers in the condition in which it was sold.

59. During or about May, 1992, Plaintiff purchased Ultrabac7/Somubac, which is the product of the Defendant, for vaccination of its cattle. The objective of the

vaccinations was to aid in the prevention of debilitating or mortal infections and diseases.

60. During or about May, 1992, the vaccine, Ultrabac7/Somubac, was shipped refrigerated to Plaintiff via United Parcel Service.

61. The said vaccine, Ultrabac7/Somubac, was kept refrigerated upon receipt by Plaintiff.

62. During or about June, 1992, Plaintiff vaccinated its cattle with the aforesaid vaccine which was in the same condition in which it was supplied to Plaintiff and The Miller Company by Defendant, SMITHKLINE BEECHAM CORPORATION.

63. At the time of vaccinating its cattle with the product of the Defendant, SMITHKLINE BEECHAM CORPORATION, Plaintiff used the vaccine in accordance with the instructions and according to the appropriate business custom.

64. At the time of the aforesaid use of the Ultrabac7/Somubac vaccine, Plaintiff intended the said vaccine to aid in the prevention of Haemophilus somnus related infections and other mortal and dangerous diseases in healthy animals, and was unaware of any defect or dangerous condition in the vaccine and expected the vaccine to be safe for use in a foreseeable manner.

65. Notwithstanding the inoculation of Plaintiff's cattle with the product of the Defendant, SMITHKLINE BEECHAM CORPORATION, Plaintiff's cattle, after the injections of mid 1992 were administered, contracted debilitating and mortal infections and diseases which

killed certain of Plaintiff's animals or so debilitated certain others as to make it necessary for Plaintiff to sell or dispose of them at a loss.

WHEREFORE, Plaintiff PRAYS for a Judgment against Defendant, SMITHKLINE BEECHAM CORPORATION, on Count VII for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

COUNT VIII – FAILURE TO WARN "STRICT LIABILITY"

66. Plaintiff incorporates into this Count VIII the allegations of paragraphs 1 through 65 of the General Allegations and the First, Second, Third, Fourth, Fifth, Sixth and Seventh Counts as though fully set forth herein.

67. The Ultrabac7/Somubac vaccine sold to Plaintiff by Defendant, SMITHKLINE BEECHAM CORPORATION, was unreasonably dangerous and in a defective condition because it was not accompanied by an adequate warning that would have allowed Plaintiff to use the product without injury to its cattle. The warning accompanying the product was inadequate in that it failed to advise Plaintiff that the use of said product in conjunction with other products could cause a dangerous immunosuppressive reaction in the cattle resulting in the illness and/or death of the cattle.

68. As a result of the defective and unreasonably dangerous condition of the Ultrabac7/Somubac vaccine,

Plaintiff incurred damage in the manner previously alleged.

WHEREFORE, Plaintiff PRAYS for a Judgment against Defendant, SMITHKLINE BEECHAM CORPORATION, on Count VIII of the Complaint for an amount in excess of $50,000, plus interest thereon at the highest legal rate, plus punitive damages, plus reasonable attorneys fees, plus the costs of this action.

PLAINTIFF DEMANDS A TRIAL BY JURY UNDER FED. R. CIV. P. 38.

LYNNBROOK FARMS, an Illinois General partnership

By: /s/ Matthew C. Potts
Matthew C. Potts

MATTHEW C. POTTS
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and

JAMES A. DAVIS
WISEMAN LAW OFFICES
Suite 202-505 Building
505 North Main Street
Fremont, Nebraska 68025
Telephone: (402) 727-5577

/lit/lynnbr.lit

CERTIFICATE OF SERVICE

I, Matthew C. Potts, an Attorney for Plaintiff, hereby Certify under penalties as provided by law, that I served the foregoing Amended Complaint upon the Registered Agent for the Defendants therein by enclosing two (2) copies of the same in an envelope plainly addressed as follows:

SMITHKLINE BEECHAM CORPORATION and
NORDEN LABORATORIES, INC. a/k/a
SMITHKLINE BEECHAM CORPORATION
c/o CT CORPORATION
208 South LaSalle Street
Chicago, IL 60604

and by depositing said envelope with first-class postage fully prepaid in a United States mailbox at Elmwood, Illinois, on this 3rd day of June, 1994.

/s/ Matthew C. Potts
Matthew C. Potts

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
PEORIA DIVISION

LYNNBROOK FARMS, an Illinois General Partnership,	)	
Plaintiff,	)	Case No. 94-CV-1227
v.	)	
SMITHKLINE BEECHAM CORPORATION, and NORDEN LABORATORIES, INC.,	)	
Defendants.	)	

AFFIDAVIT OF CYRIL G. GAY, D.V.M., Ph.D.

STATE OF NEBRASKA)
) SS.
COUNTY OF LANCASTER)

Cyril G. Gay, D.V.M., Ph.D., being duly sworn upon his oath, deposes and states as follows:

1. I am an adult witness legally competent to testify in this matter as to the items set forth below, which are based upon my personal knowledge and my review of certain business records maintained by SmithKline Beecham Animal Health, an unincorporated division of SmithKline Beecham Corporation ("SBC").

2. I am currently employed by SBC as its Associate Director, Biological Regulatory Affairs, Worldwide. In that capacity, I am familiar with the licenses obtained by SBC from the Animal and Plant Health Inspection Service

("APHIS") of the United States Department of Agriculture ("USDA") for the animal vaccines involved in this litigation. I am also familiar with the regulations promulgated and enforced by APHIS governing the design, manufacture, distribution, testing and labelling of animal vaccines.

3. APHIS' mandate is to ensure that all animal vaccines prepared and marketed in the United States are *pure, safe, potent,* and *efficacious.* 9 C.F.R. § 113.5(a) (1994). To ensure that these goals are satisfied. APHIS has established a complex regulatory program governing the design, manufacture, distribution, testing, and labelling of animal vaccines. *See* 9 C.F.R. §§ 101-124 (1994). Under both VSTA and the regulations promulgated thereunder, establishments at which animal vaccines are manufactured must be licensed by APHIS. 21 U.S.C.A. §§ 151, 154 (West Supp. 1994); 9 C.F.R. § 102.2 (1994). In addition, every animal vaccine manufactured and distributed in the United States must be licensed by APHIS before it may be marketed. 21 U.S.C.A. § 151 (West Supp. 1994); 9 C.F.R. § 102.1 (1994).

4. The first step in the process for a manufacturer seeking licensure of an animal vaccine is the preparation of an Outline of Production. *See* 9 C.F.R. §§ 114.8, 114.9 (1994). The Outline of Production must contain detailed highly technical data on every step in the design, manufacture, packaging and testing of all animal vaccines. *See* 9 C.F.R. § 114.9(d) (1994). The Outline of Production must be specifically approved by APHIS as a condition to product licensure. 9 C.F.R. §§ 102.5(d)(1), 114.8(a) (1994). No changes may be made in an approved Outline of

Production without prior approval from APHIS. 9 C.F.R. § 102.5(d)(1) (1994).

5. Among the mandatory prerequisites to licensure is satisfaction of an elaborate, APHIS-specified testing protocol. *See* 9 C.F.R. Part 113 (1994). APHIS requires detailed tests by which the licensee must assure the purity, safety, potency and efficacy of the product. *See, e.g.*, the Standard Procedures found at 9 C.F.R. §§ 113.25-55 (1994) for safety and purity, and the specific tests required to assure potency and efficacy of bacterial and viral animal vaccines found at 9 C.F.R. §§ 113.64-332 (1994). Where a proposed vaccine contains several different viral or bacterial fractions,[1] not only must the overall product be tested as required by APHIS, each individual fraction must be fully tested as if each were to be manufactured and distributed as a separate product. 9 C.F.R. § 113.7(a) (1994). All test and research reports must be submitted to APHIS for its review prior to licensure. 9 C.F.R. § 102.3(b)(2)(ii) (1994).

6. In addition to testing requirements, APHIS has also prescribed extensive standards for the labelling of animal vaccines. *See* 9 C.F.R. § 112 (1994). APHIS requires all animal vaccines to contain certain mandatory information on all labels, including the container label, the carton label, and any product insert, circular or leaflet. 9 C.F.R. § 112.2 (1994). The manufacture must submit all label text and design features, in final format, to APHIS prior to licensure. 9 C.F.R. § 102.3(b)(2)(iv) (1994). All proposed

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[1] A "fraction" is a specific viral or bacterial antigen which constitutes a component of an overall biological product. 9 C.F.R. § 101.3(f) (1994).

labels must be reviewed for compliance with the regulations and specifically approved in writing by APHIS, and *only* approved labels may accompany veterinary biologics sold on the marketplace. 9 C.F.R. § 112.5(c) (1994). If a manufacturer of a licensed product seeks to alter in any manner an already-approved label, APHIS must review and specifically approve the modified label before it may be used. *Id.*

7. Once all necessary pre-licensure testing required by APHIS has been completed and the product label has been specifically approved. APHIS may then issue a license for the particular vaccine. *See* 9 C.F.R. § 102.3(b) (1994). Such does *not*, however, automatically permit the vaccine to be released for sale. Before any serial, or lot, of vaccine may be sold, each serial must be tested by the manufacturer or by APHIS for purity, safety, potency and efficacy. *See* 9 C.F.R. §§ 113.3 (sampling of products), 113.5(a) (general testing), 113.6 (APHIS testing). If unsatisfactory results are obtained either by APHIS or the manufacturer, the serial may *not* be released into the market. 9 C.F.R. § 113.6(b) (1994).

8. I have personally reviewed the applications made by SBC to APHIS to obtain licenses for the animal vaccines involved in this litigation. A true and correct copy of the license issued by APHIS on January 6, 1989, under USDA License No. 1187.21 for *CattleMaster 4 is attached hereto as Exhibit A. A true and correct copy of the license issued by APHIS on December 5, 1985, bearing USDA License No. 4723.00 for Ultrabac7/Somubac is attached hereto as Exhibit B.

9. Each of the SBC vaccines involved in this litigation, through the licensure process and through post-licensure testing and evaluation, has been determined by APHIS to satisfy all requirements for purity, safety, potency, and efficacy contained in the APHIS standards. Each has been designed, manufactured and tested pursuant to APHIS standards, and of necessity APHIS approved the content and sufficiency of all design, manufacturing and testing data submitted prior to licensure of each vaccine. In addition, the text, layout, and design of all labelling on these vaccines, including the packaging and product inserts, have been specifically approved in writing by APHIS.

FURTHER AFFIANT SAITH NOT.

/s/ Cyril G. Gay
Cyril G. Gay, D.V.M., Ph.D.

Subscribed and sworn to before me
this 28th day of October, 1994.

/s/ Nancy Hock
Notary Public

GENERAL NOTARY-
State of Nebraska
NANCY HOCK
My Comm. Exp. Feb. 14, 1997

EXHIBIT A

CONFIDENTIAL

UNITED STATES
DEPARTMENT OF AGRICULTURE

UNITED STATES VETERINARY BIOLOGICAL PRODUCT LICENSE

Washington, D.C.,

January 6, 1989

This to Certify that, pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, the person holding United States Veterinary Biologics Establishment License No. 189 *is authorized to prepare in the facilities designated in the establishment license:*

BOVINE RHINOTRACHEITIS-VIRUS
DIARRHEA-PARAINFLUENZA$_3$-
RESPIRATORY SYNCYTIAL VIRUS VACCINE

Modified Live and Killed Virus

Code 1187.21

Preparation shall be in accordance with the provisions of the Act, the regulations made thereunder, and additional restrictions or requirements when listed below.

This license is subject to termination as provided in the regulations made under the authority contained in said Act, and to

suspension or revocation if the licensee violates or fails to comply with said Act or the regulations made thereunder.

/s/ Terry L. Medley
Animal and Plant Health
Inspection Service
Acting Director
Biotechnology, Biologics, and
Environmental Protection

EXHIBIT B

CONFIDENTIAL

UNITED STATES
DEPARTMENT OF AGRICULTURE

UNITED STATES VETERINARY BIOLOGICAL PRODUCT LICENSE

Washington, D.C.,

December 5, 1985

This to Certify that, pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, the person holding United States Veterinary Biologics Establishment License No. 225 is authorized to prepare in the facilities designated in the establishment license:

CLOSTRIDIUM CHAUVOEI-SEPTICUM-NOVYI-SORDELLII-PERFRINGENS

TYPES C & D-HAEMOPHILUS SOMNUS BACTERIN-TOXOID

Code 7423.00

Preparation shall be in accordance with the provisions of the Act, the regulations made thereunder, and additional restrictions or requirements when listed below.

This license is subject to termination as provided in the regulations made under the authority contained in said Act, and to suspension or revocation if the licensee violates or fails to comply with said Act or the regulations made thereunder.

SM 02023

/s/ B.J. Fichtner
Acting Deputy Adminstrator,
Veterinary Services
Animal and Plant Health
Inspection Service

LAW OFFICES

WHITNEY & POTTS, LTD.
118 WEST MAIN STREET
PO BOX 368
ELMWOOD, ILLINOIS 61529-0368

TELEPHONE 742-2591 OR 742-3611
FAX 742-8684
AREA CODE 309

ROBERT L. POTTS

MATTHEW C. POTTS
ASSOCIATE

L. RICHARD WHITNEY
(1908-1965)
GEORGE I. WHITNEY
(1938-1987)

February 1, 1995

Janell M. Gabor, Esq.
Scott A. Smith, Esq.
POPHAM, HAIK, SCHNOBRICH &
KAUFMAN, LTD.
3300 Piper Jaffray Tower
222 Ninth Street South
Minneapolis, MN 55402

Re: Lynnbrook Farms vs. Smithkline Beecham; Case No. 94-CV-1227; Stipulation for Stay of Application of Rule 26.

Dear Ms. Gabor and Mr. Smith:

Please be advised that we are in receipt of your Entry of Appearance which was recently filed with the Court, and we look forward to working with you towards the resolution of the above-captioned case.

Also, we have enclosed herewith a Stipulation For An Order to Stay the Application of Rule 26 During the Pendency of Defendant's Motion To Dismiss and Motion for Summary Judgment since it has recently come to our

attention that it is proper in the Central District of Illinois to stay the application of this Rule while Motions such as those filed herein are pending. A Stipulation such as this would be mutually beneficial to both of our firms and our clients so that time will not have to be spent on discovery until we know exactly what the results of the Motions will be.

If you have any questions in this regard, then please do not hesitate to contact our office. Otherwise, please execute the Stipulation and return the same to our office as soon as possible so that we may have it filed. Thank you for your anticipated cooperation.

Respectfully,

WHITNEY & POTTS, LTD.

/s/ Matthew C. Potts
Matthew C. Potts

MCP:jc
Enclosure
/lit/lynnbr.stp

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
PEORIA DIVISION

LYNNBROOK FARMS, an Illinois General Partnership, Plaintiff, v. SMITHKLINE BEECHAM CORPORATION, and NORDEN LABORATORIES, INC., Defendants.	)	Case No. 94-CV-1227

STIPULATION FOR AN ORDER TO STAY THE APPLICATION OF RULE 26 DURING THE PENDENCY OF DEFENDANT'S MOTION TO DISMISS AND MOTION FOR SUMMARY JUDGMENT

(Filed Feb. 15, 1995)

NOW COME the Plaintiff, LYNNBROOK FARMS, by and through its Attorneys, WHITNEY & POTTS, LTD., and the Defendant, SMITHKLINE BEECHAM CORPORATION, by and through its Attorneys, POPHAM, HAIK, SCHNOBRICH & KAUFMAN, LTD., and they do hereby stipulate and agree in substance and in form to the entry of the following Order to stay the application of Rule 26

during the pendency of Defendant's Motion To Dismiss and Motion For Summary Judgment.

LYNNBROOK FARMS,
an Illinois General
Partnership

By: /s/ Matthew Potts
One of its
Attorneys

WHITNEY & POTTS, LTD.
Attorneys for Plaintiff
118 West Main Street
P. O. Box 368
Elmwood, IL 61529-0368
Telephone: (309) 741-2591

SMITHKLINE BEECHAM
CORPORATION,

By: /s/ Janell Gabor
One of its
Attorneys

POPHAM, HAIK,
SCHNOBRICH &
KAUFMAN, LTD.,
Attorneys for Defendant
3300 Piper Jaffray Tower
222 Ninth Street South
Minneapolis, MN 55402
Telephone: (612) 333-4800

94-1227
Lynnbrook Farms
v.
Smithline

ORDER

(Filed Feb. 15, 1995)

Pursuant to the foregoing Stipulation of the parties hereto, it is hereby Ordered that the application of Rule 26 be stayed during the pendency of Defendant's Motion To Dismiss and Motion For Summary Judgment

ENTERED this 15th day of February , 1995.

/s/ Michael M. Mihm
JUDGE

[LOGO]

United States Department of Agriculture | Animal and Plant Health Inspection Service | Washington, D.C. 20250

December 22, 1995

Honorable Paul David Wellstone
United States Senator
417 Litchfield Avenue, SW.
Willmar, Minnesota 55201

Dear Senator Wellstone:

Thank you for your letter of December 6, 1995, on behalf of your constituents Randy and Patty Brandt of Marshall, Minnesota, concerning their lawsuit against a USDA licensed manufacturer of veterinary biological products. Your letter requested a written clarification of the scope of our preemption of State law under the Virus-Serum-Toxin Act (VSTA), 21 U.S.C. 151 *et seq.*

On October 19, 1990, we published a proposed rule in the *Federal Register* (55 FR 42392). The purpose of the proposed rule was to clarify our regulations with respect to State restrictions on the use and distribution of veterinary biological products and to specify how a person could request that Federal restrictions be imposed on such products.

On August 27, 1992, we published our final rule (57 FR 38758). A copy of that rule is enclosed for your information. We stated in that rule that in order to maintain uniform national standards regarding veterinary biological products (including labeling), States are not free to

impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. We promulgated this rule in response to regulatory actions by certain States which attempted to impose requirements concerning USDA licensed veterinary biological products which were different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product.

Our intent in promulgating the rule was, and continues to be, to preempt states from imposing requirements either through statutes, regulations, or other means that are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Such requirements would include, but are not limited to production, testing, distribution, or labeling requirements. We did not intend to preempt common law actions for damages arising from noncompliance with USDA regulatory standards.

Sincerely,

/s/ Terry L. Medley
Terry L. Medley
Acting Administrator

Enclosure

UNITED STATES COURT OF APPEALS *jc*

For the Seventh Circuit
Chicago, Illinois 60604

August 5, 1996

Before

Hon. JOEL M. FLAUM, *Circuit Judge*

LYNNBROOK FARMS, an Illinois General Partnership, Plaintiff-Appellant,	] Appeal from the United States District Court for the Central District of Illinois, Peoria Division.
No. 95-2051 v.	] No. 94 C 1227
SMITHKLINE BEECHAM CORPORATION, Defendant-Appellee.	] Michael M. Mihm, Chief Judge.

Upon consideration of:

1. **MOTION TO RECALL MANDATE** filed July 10, 1996, by counsel for the appellant;

2. **APPELLEE'S MEMORANDUM OF LAW IN OPPOSITION TO APPELLANT'S MOTION TO RECALL MANDATE** filed July 22, 1996, by counsel; and

3. July 25, 1996 letter to the clerk from counsel for the appellee;

We have jurisdiction to consider the motion to recall the mandate, which is **DENIED.**

United States Constitution, Article VI, cl. 2

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties, made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

21 U.S.C. § 151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments

It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the United States, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

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§ 152. Importation regulated and prohibited.

The importation into the United States of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any

worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, is prohibited without (1) a permit from the Secretary of Agriculture, or (2) in the case of an article originating in Canada, such permit or, in lieu of such permit, such certification by Canada as may be prescribed by the Secretary of Agriculture.

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§ 153. Inspection of imports; denial of entry and destruction

The Secretary of Agriculture is hereby authorized to cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are being imported or offered for importation into the United States, to determine whether such viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful, and if it shall appear that any such virus, serum, toxin, or analogous product for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer.

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§ 154. Regulations for preparation and sale; licenses

The Secretary of Agriculture is hereby authorized to make and promulgate from time to time such rules and

regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals or otherwise to carry out this paragraph, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals intended for sale, barter, exchange, or shipment as aforesaid.

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§ 154a. Special licenses for special circumstances; expedited procedure; conditions; exemptions; criteria

In order to meet an emergency condition, limited market or local situation, or other special circumstance (including production solely for intrastate use under a State-operated program), the Secretary may issue a special license under an expedited procedure on such conditions as are necessary to assure purity, safety, and a reasonable expectation of efficacy. The Secretary shall exempt by regulation from the requirement of preparation pursuant to an unsuspended and unrevoked license any virus, serum, toxin, or analogous product prepared by any person, firm, or corporation –

(1) solely for administration to animals of such person, firm, or corporation;

(2) solely for administration to animals under a veterinarian-client-patient-relationship in the course of the State licensed professional practice of veterinary medicine by such person, firm, or corporation; or

(3) solely for distribution within the State of production pursuant to a license granted by such State under a program determined by the Secretary to meet criteria under which the State –

(A) may license virus, serum, toxin, and analogous products and establishments that produce such products;

(B) may review the purity, safety, potency, and efficacy of such products prior to licensure;

(C) may review product test results to assure compliance with applicable standards for purity, safety, and potency, prior to release to the market;

(D) may deal effectively with violations of State law regulating virus, serum, toxin, and analogous products; and

(E) exercises the authority referred to in subclauses (A) through (D) consistent with the intent of this paragraph of prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous products.

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§ 155. Permits for importation

The Secretary of Agriculture is hereby authorized to issue permits for the importation into the United States of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous, or harmful.

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§ 156. Licenses conditioned on permitting inspection; suspension of licenses

All licenses issued under authority of this chapter to establishments where such viruses, serums, toxins, or analogous products are prepared for sale, barter, exchange, or shipment as aforesaid, shall be issued on condition that the licensee shall permit the inspection of such establishments and of such products and their preparation; and the Secretary of Agriculture may suspend or revoke any permit or license issued under authority of said chapter, after opportunity for hearing has been granted the licensee or importer, when the Secretary of Agriculture is satisfied that such license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, or shipment as aforesaid, or the importation into the United States of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals.

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§ 157. Same; inspection daytime or nighttime

Any officer, agent, or employee of the Department of Agriculture duly authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid.

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§ 158. Offenses; punishment

Any person, firm, or corporation who shall violate any of the provisions of this chapter shall be deemed guilty of a misdemeanor, and shall, upon conviction, be punished by a fine of not exceeding $1,000 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

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§ 159. Enforcement penalties applicable; Congressional findings

The procedures of sections 672, 673, and 674 of this title (relating to detentions, seizures and condemnations, and injunctions, respectively) shall apply to the enforcement of this chapter with respect to any product prepared, sold, bartered, exchanged, or shipped in violation of this chapter or a regulation promulgated under this

chapter. The provisions (including penalties) of section 675 of this title shall apply to the performance of official duties under this chapter. Congress finds that (i) the products and activities that are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce or the free flow thereof, and (ii) regulation of the products and activities as provided in this chapter is necessary to prevent and eliminate burdens on such commerce and to effectively regulate such commerce.